MAR 19 2000

Summary Information

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K000566.

1.	**Submitter name, address, contact**	Ortho-Clinical Diagnostics, Inc. 100 Indigo Creek Drive Rochester, New York 14626-5101 (716) 453-4041 Contact Person: Joseph Falvo
2.	**Preparation date**	Date Special 510(k) prepared: 18 February 2000
3.	**Device name**	Trade or Proprietary Name: VITROS Immunodiagnostic Products PSA Reagent Pack VITROS Immunodiagnostic Products PSA Calibrators Common Name : PSA assay Classification Name: test for the *in vitro* quantitative determination of prostate specific antigen in serum or plasma.
4.	**Predicate device**	The VITROS Immunodiagnostic Products PSA Reagent Pack (new formulation) and VITROS Immunodiagnostic Products PSA Calibrators (new formulation) are substantially equivalent to the VITROS Immunodiagnostic Products PSA Reagent Pack (original formulation) and VITROS Immunodiagnostic Products PSA Calibrators (original formulation).

Continued on next page

5. Device description

The VITROS Immunodiagnostic System uses luminescence as the signal in the quantitative and semi-quantitative determination of selected analytes in human body fluids, commonly serum and plasma. Coated microwells are used as the solid phase separation system.

The system is comprised of three main elements:

1. The VITROS Immunodiagnostic Products range of immunoassay products (in this case VITROS Immunodiagnostic Products PSA Reagent Pack, VITROS Immunodiagnostic Products PSA Calibrators) which are combined by the VITROS Immunodiagnostic System to perform the VITROS PSA assay.

2. The VITROS Immunodiagnostic System – instrumentation, which provides automated use of the immunoassay kits. The VITROS Immunodiagnostic System was cleared for market by a separate 510(k) pre-market notification (K962919).

3. Common reagents used by the VITROS System in each assay. The VITROS Immunodiagnostic Products Signal Reagent and VITROS Immunodiagnostic Products Universal Wash Reagent were cleared as part of the VITROS Immunodiagnostic Products Total T3 Reagent Pack and VITROS Immunodiagnostic Products Total T3 Calibrators 510(k) premarket notification (K964310).

The VITROS System and common reagents are dedicated specifically for use only with the VITROS Immunodiagnostic Products range of immunoassay products.

6. Device intended use

VITROS PSA Reagent Pack
For in vitro diagnostic use only.
The VITROS PSA Reagent Pack quantitatively measures prostate-specific antigen (PSA) concentration in human serum and plasma to aid in the management of patients with prostate cancer.

VITROS PSA Calibrators - For *in vitro* use in the calibration of the VITROS Immunodiagnostic System for the quantitative measurement of PSA in human serum and plasma.

Continued on next page

7. Comparison to predicate device

The VITROS Immunodiagnostic Products PSA Reagent Pack (new formulation) and VITROS Immunodiagnostic Products PSA Calibrators (new formulation) are substantially equivalent to VITROS Immunodiagnostic Products PSA Reagent Pack for use with human serum or plasma (EDTA or heparin) which was cleared by the FDA (K984289) for in vitro diagnostic use.

Table 1 lists the characteristics of the assays performed using the VITROS PSA assay (new formulation) and the VITROS PSA assay (original formulation).

Table 1 List of Assay Characteristics Comparison to Predicate Device

Device Characteristic	New Device VITROS PSA assay (New formulation)	Predicate Device VITROS PSA assay (Original formulation)
Preservative Formulation	0.5% 2-chloro-acetamide	0.1% 2-chloro-acetamide
Calibration range	0-100 ng/mL	0-100 ng/mL
Basic principle	Solid phase immunoassay	Solid phase immunoassay
Tracer	Enzyme labeled	Enzyme labeled
Antibody	1) Two mouse monoclonal anti-PSA antibodies in biotinylated antibody reagent 2) Goat polyclonal anti-PSA antibody in conjugate reagent	1) Two mouse monoclonal anti-PSA antibodies in biotinylated antibody reagent 2) Goat polyclonal anti-PSA antibody in conjugate reagent
Instrumentation	VITROS Immunodiagnostic System	VITROS Immunodiagnostic System
Sample type	Serum and plasma (EDTA or heparin).	Serum and plasma (EDTA or heparin).
Sample volume	15µL	15µL
Incubation time and temperature	30 minutes at 37°C with shaking	30 minutes at 37°C with shaking

Continued on next page

8. Conclusions The information presented in the pre-market notification demonstrate that the performance of the VITROS PSA assay (new formulation) for use with human serum and plasma (EDTA or heparin) is substantially equivalent to the cleared predicate device.

Equivalence was demonstrated using manufactured reagents along with patient samples with measured PSA values spanning the assay range.

The information presented in the premarket notification provide a reasonable assurance that the VITROS PSA assay (new formulation) for use with human serum and plasma (EDTA or heparin) is safe and effective for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

MAR 9 2000

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Joseph Falvo
Regulatory Affairs Associate
Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101

Re: K000566
Trade Name: VITROS Immunodiagnostic Products PSA Reagent Pack and VITROS Immunodiagnostic Products PSA Calibrators
Regulatory Class: II
Product Code: LTJ
Dated: February 18, 2000
Received: February 22, 2000

Dear Mr. Falvo:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement of Intended Use

510(k) Number (if known): K000566

Device Name:

VITROS Immunodiagnostic Products PSA Reagent Pack
VITROS Immunodiagnostic Products PSA Calibrators

Indications for Use:

VITROS PSA Reagent Pack
For in vitro diagnostic use only.
The VITROS PSA Reagent Pack quantitatively measures prostate-specific antigen (PSA) concentration in human serum and plasma to aid in the management of patients with prostate cancer.

VITROS PSA Calibrators - For *in vitro* use in the calibration of the VITROS Immunodiagnostic System for the quantitative measurement of PSA in human serum and plasma.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E. Maksim

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K000566

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)